# UNITED STATES PATENT AND TRADEMARK OFFICE

## BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte D. WADE WALKE
and NATHANIEL L. WILGANOWSKI



Appeal No. 2005-2030
Application No. 09/783,669

ON BRIEF

Before SCHEINER, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

## DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-7, all of the claims in the application. Claims 2-4 are representative and read as follows:

2. An expression vector comprising a nucleic acid sequence encoding the amino acid sequence shown in SEQ ID NO:4.

3. An expression vector comprising a nucleic acid sequence encoding the amino acid sequence shown in SEQ ID NO:2.

4. An expression vector comprising a nucleic acid sequence encoding the amino acid sequence shown in SEQ ID NO:6.

The examiner relies on the following references:

Ji et al., "G Protein-coupled Receptors," Journal of Biological Chemistry, Vol. 273, No. 28, pp. 17299-17302 (1998)

Bork et al, "Predicting functions from protein sequences – where are the bottlenecks?," Nature Genetics, Vol. 18, pp. 313-318 (1998)

Yan et al., "Two-Amino Acid Molecular Switch in an Epithelial Morphogen That Regulates Binding to Two Distinct Receptors," Science, Vol. 290, pp. 523- 527 (2000)

Skolnick et al., "From genes to protein structure and function: novel applications of computational approaches in the genomic era," TIBTECH, Vol. 18, pp. 34-39 (2000)

Barry et al., Introduction to Proteins and Protein Engineering, Elsevier, p. 41 (1986)

Claims 1-7 stand rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as lacking patentable utility.

We affirm.

## Background

"[M]embrane receptor proteins are often involved in signal transduction pathways that control cell physiology, chemical communication, and gene expression. A particularly relevant class of membrane receptors are those typically characterized by the presence of 7 conserved transmembrane domains. . . . Such, '7TM receptors' include a superfamily of receptors known as G-protein coupled receptors (GPCRs)." Specification, page 1. "The present invention relates to the discovery, identification, and characterization of nucleotides that encode novel GPCRs, and the corresponding novel GPCR (NGPCR) amino acid sequences. The NGPCRs . . . are transmembrane proteins that span the cellular membrane and are involved in signal transduction after ligand binding." Page 2.

"The described NGPCR sequences are apparently encoded within a single coding exon (which may include one or more introns that can be spliced-out in certain cells or tissues) that can be used to produce the described sequences." Page 6.

The specification does not say what ligands bind to the disclosed GPCRs, or what signal is putatively transduced by the proteins, or what role the proteins play in any physiological process. Nonetheless, the specification discloses that the proteins of SEQ ID NO's 2, 4, and 6, and nucleic acids encoding them, have several uses. For example, the specification contemplates "methods . . . for the identification of compounds that modulate, i.e., act as agonists or antagonists, of NGPCR gene expression and/or NGPCR gene product activity. . . . Such compounds can be used as therapeutic agents for the treatment of various symptomatic representations of biological disorders or imbalances." Page 3.

The specification also states that "NGPCR proteins, polypeptides and peptide fragments, mutated, truncated or deleted forms of the NGPCR and/or NGPCR fusion proteins can be prepared for a variety of uses. These uses include but are not limited to the generation of antibodies, as reagents in diagnostic assays, the identification of other cellular gene products related to a NGPCR, as reagents in assays for screening for compounds that can be used as pharmaceutical reagents useful in the therapeutic treatment of mental, biological, or medical disorders (i.e., heartbeat rate, etc.) and disease." Page 16.

Discussion

The examiner rejected all of the claims as lacking a disclosed utility sufficient to satisfy 35 U.S.C. § 101.[1] The examiner bears the initial burden of showing that a claimed invention lacks patentable utility. See In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.").

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. See In re Fisher, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005). The Fisher court interpreted Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility." 421 F.3d at 1370, 76 USPQ2d at 1229. The Fisher court held that § 101 requires a utility that is both substantial and specific. Id. at 1371, 76 USPQ2d at 1229. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." Id., 76 USPQ2d at 1230.

The court held that a specific utility is "a use which is not so vague as to be meaningless." Id. In other words, "in addition to providing a 'substantial' utility, an

[1] The examiner also rejected all of the claims under 35 U.S.C. § 112, first paragraph, for lack of enablement, but that rejection is merely as a corollary of the finding of lack of utility. See the Examiner's Answer, page 6. Therefore, our conclusion with respect to the § 101 issue also applies to the § 112 issue.

asserted use must also show that that claimed invention can be used to provide a well-defined and particular benefit to the public." Id.

The Fisher court held that none of the uses asserted by the applicant in that case were either substantial or specific. The uses were not substantial because "all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world." Id. at 1373, 76 USPQ2d at 1231. "Consequently, because Fisher failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the '643 application, we have no choice but to conclude that the claimed ESTs do not have a 'substantial' utility under § 101." Id. at 1374, 76 USPQ2d at 1232.

"Furthermore, Fisher's seven asserted uses are plainly not 'specific.' Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. . . . Nothing about Fisher's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the '643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101." Id.

In this case, the examiner found the specification's disclosure to be inadequate:

> The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.
> . . .
> The instant claims are drawn to a DNA and the protein encoded thereby of as yet undetermined function or biological significance. . . . [I]n the absence of knowledge of the biological significance of this specific

> polynucleotide and encoded protein, there is no immediately obvious patentable use for the polynucleotide or the encoded protein.

Examiner's Answer, pages 3-4. The examiner concluded that "[t]o employ a polynucleotide of the instant invention in any of the disclosed methods would clearly be using it as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability." Id., page 6.

Appellants argue that the claimed nucleic acids encode a protein with a high degree of similarity to known GPCRs and that "fully 60% of licensed drugs target G-protein coupled receptors (Gurrath, 2001, Curr. Med. Chem. 8:1605-1648 . . .)." Appeal Brief, pages 4-5. Appellants also argue that the issuance of other patents supports the patentable utility of GPCRs. Id., page 5.[2]

We do not agree that the characterization of the claimed nucleic acids as encoding G protein-coupled receptors is sufficient to establish their utility. The specification states that "membrane receptor proteins are often involved in signal transduction pathways that control cell physiology, chemical communication, and gene expression." Page 1. The specification provides no information regarding what specific biological functions or activities involve the polypeptides encoded by the instantly claimed nucleic acids, or what ligands bind to the proteins of SEQ ID NOs 2, 4, or 6, or what signal (if any) is transduced by the proteins in response to ligand binding.

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[2] Appellants also argue that the utility of the instantly claimed sequences is supported by their similarity to a protein designated MRGX2, which is described in GenBank record number NP_473371. Appeal Brief, page 4. However, Appellants have pointed to no evidence that the GenBank record they rely on, or other evidence describing MRGX2, was available to those skilled in the art as of this application's effective filing date (February 18, 2000). "Enablement, or utility, is determined as of the application filing date." Brana, 51 F.3d at 1567 n.19, 34 USPQ2d at 1441 n.19. Since the evidence pertaining to MRGX2 does not appear to have been known to those skilled in the art when this application was filed, Appellants cannot rely on it to establish the patentable utility of the presently claimed nucleic acids.

Thus, the record does not support Appellants' position that the characterization of a polypeptide as a G protein-coupled receptor would have suggested a specific biological function, or any other basis for patentable utility, to a person skilled in the art at the time the application was filed. In the terms used by the Fisher court, such a characterization does not provide a substantial utility because it does not show that the claimed invention is useful as disclosed in its current form, only that it may be useful at some future date after further research: the specification does not disclose a significant and presently available benefit to the public. Cf. Fisher, 421 F.3d at 1371, 76 USPQ2d at 1230. Mere characterization as a GPCR also fails to provide a specific utility, because it does not "provide a well-defined and particular benefit to the public." Id.

Appellants also cite two U.S. Patents that they characterize as disclosing GPCR-related products and methods.[3] Appellants conclude that "[t]he issuance of these U.S. patents clearly indicates that G protein-coupled receptor polynucleotides have utility." Appeal Brief, page 5.

The cited patents do not show that the present claims are patentable. First, U.S. Patent 6,043,052 cannot be relied on to show the state of the art as of this application's filing, because it issued after the effective filing date. See In re Glass, 492 F.2d 1228, 1231, 181 USPQ 31, 34 (CCPA 1974) ("[T]he contents of a patent application which may be available as 'prior art' under § 102(e) to show that another was the first inventor may not have been known to anyone other than the inventor, his attorney, and the Patent

[3] Appellants cite U.S. Patents 6,043,052 and 5,891,646. Appellants also cite U.S. Patent 6,110,693, but this patent is a continuation of 5,891,646 and therefore contains that same disclosure.

Office examiner . . . until it issued as a patent. As of its filing date it does not show what is known generally to 'any person skilled in the art,' to quote from § 112.").

Appellants characterize the remaining patent (5,891,646) as

> disclos[ing] and claim[ing] methods for detecting G protein-coupled receptor activity in vivo and in vitro, methods for assaying G protein-coupled receptor activity, and methods of screening for G protein-coupled receptor ligands, G protein-coupled receptor kinase activity, components that interact with G protein-coupled receptor regulatory processes and constructs useful in such methods.

Appeal Brief, page 5. Appellants assert that the '646 patent is "directly applicable to the present invention (G protein-coupled receptor polynucleotides) and [is] evidence that those skilled in the art recognize the specific and substantial utility of G protein-coupled receptors." Id.

Appellants overstate the relevance of the '646 patent. The patent does disclose methods for characterizing putative GPCRs and therefore is evidence of the potential utility of such proteins. The examiner has not disputed that some GPCRs, when characterized, have patentable utility. See the Examiner's Answer, page 3: "There is little doubt that, after complete characterization, this DNA and encoded protein may be found to have a specific and substantial credible utility." However, the fact that some GPCRs have patentable utility does not establish that the presently claimed putative GPCR has utility, even absent any disclosure of its ligand(s) or biological role. We find that the instant disclosure is inadequate to establish any specific and substantial, patentable utility for the presently claimed polynucleotides.

Finally, Appellants argue that "the present nucleotide sequence would be an ideal, novel candidate for assessing gene expression using, for example, DNA chips" (Appeal

Brief, page 12); that "the present polynucleotide provides exquisite specificity in localizing the specific region of the human chromosome containing the gene encoding the given polynucleotide" (id., page 15); and that "the described sequences are useful for functionally defining exon splice-junctions" (id., page 16).

We find that none of these uses meet the requirements of § 101. In this case, as in Fisher, the generic uses asserted by Appellants – assessing gene expression, mapping human chromosomes, and identifying exon sequences – are neither substantial nor specific. Like in Fisher, these uses are "merely hypothetical possibilities, objectives which the claimed [cDNAs], or any [cDNA] for that matter, could possibly achieve, but none for which they have been used in the real world." Fisher, 421 F.3d at 1373, 76 USPQ2d at 1231 (emphasis in original). Therefore, they are not substantial utilities.

Nor are they specific utilities, because they could be asserted for any cDNA transcribed from any gene in the human genome. Because nothing about Appellants' asserted utilities sets the claimed nucleic acids apart from any other human cDNA, Appellants have "only disclosed general uses for [the] claimed [cDNAs], not specific ones that satisfy § 101." Id. at 1374, 76 USPQ2d at 1232.

Summary

The specification does not disclose a specific and substantial utility for the claimed nucleic acids, as required by 35 U.S.C. § 101. We therefore affirm the examiner's rejection of claims 1-7.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Toni R. Scheiner )
Administrative Patent Judge )
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)
Donald E. Adams ) BOARD OF PATENT
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) APPEALS AND
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